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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/220,691 12/28/98 TSUJI

N 0327-0759-0

022850 HM12/0316
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EXAMINER

WEBER, J

ART UNIT

PAPER NUMBER

1651
DATE MAILED:

03/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/220,691

Applicant(s)

Tsuji et al.

Examiner
JON P. WEBER, Ph.D.

Group Art Unit
1651



Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-5 _____ is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-5 _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- *Certified copies not received: _____
- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1651

Status of the Claims

Claims 1-5 have been presented for examination.

Priority

5 Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

10 Claims 1-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

 Claim 1 recites "inhibiting hair growth, which comprises administering an inhibitor" which is vague and indefinite because where the hair growth to be inhibited is not clear, and the nature and manner of the administration of the inhibitor is unclear.

15 Claim 2 is so confounded that it is difficult to determine what exactly is being claimed. It is surmised that what may be intended is that the inhibitors of elastase as used in the method of claim 1 are not inhibitors of matrix metalloproteases.

 Claim 5 recites "area" which is vague and indefinite because it is not clear if this is on a subject or some other location, even areas where hair would not normally be expected.

Art Unit: 1651

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mato et al.

10 (EP 166337).

Mato et al. (EP 166337) disclose that elastase activity correlates with and is associated with the stimulation of hair growth in the hair growth cycle. It was suggested that elastase inhibits premature degeneration and depilation (page 8). It was found that topical application of elastase in a cosmetic composition could promote outgrowth of new hairs and foster outgrown hairs.

15 Mato et al. (EP 166337) lack inhibiting hair growth by inhibiting elastase.

A person of ordinary skill in the art at the time the invention was made would have been motivated to inhibit elastase and thereby inhibit hair growth because it is well established in biochemical pathways, that one can promote a pathway by adding exogenous metabolite or an agent that stimulates endogenous metabolite or one can inhibit a pathway by blocking or inhibiting
20 the endogenous metabolite.

In the instant case, the metabolite is elastase. Adding exogenous elastase stimulates the hair growth cycle consistent with the role identified by Mato et al. (EP 166337) of elastase activity being associated the growth of hair in the hair growth cycle (the same observation as

Art Unit: 1651

instantly made.) Similarly, a person of ordinary skill in the art would reasonably expect on the basis of standard biochemical experience and sound scientific reasoning that inhibiting elastase would inhibit the hair growth cycle. This reasoning is supported by the state-of-the-art references provided herewith that establish that inhibiting a metabolic enzyme involved with the stimulation
5 of hair growth results in inhibiting hair growth.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to topically administer an inhibitor of elastase to an area of skin, for example, so as to inhibit hair growth in that area with a reasonable expectation of success.

Other references cited by examiner but not relied upon are cited to establish the state of
10 the art

No claims are allowed.

Any inquiry concerning this communication should be directed to Jon P. Weber, Ph.D. at
15 telephone number (703) 308-4015. The examiner can normally be reached during the hours of 07:30 to 17:30 Eastern (off first Friday).

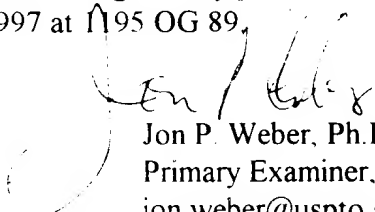
If attempts to reach the examiner by telephone are unsuccessful, a message may be left on the voice mail. The fax number for Art Unit 1651 is (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group
20 receptionist whose telephone number is (703) 308-0196. My supervisor, Michael Wityshyn, may be contacted at (703) 308-4743.

All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified or exchanged
25 unless there is of record an express waiver of the confidentiality requirements of 35 U.S.C. 122 by

Art Unit: 1651

the applicant. See the Interim Internet Usage Policy published in the Patent and Trademark Office Official Gazette on 25 February 1997 at 195 OG 89.
J.P.W. 9 March 2000

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